

17

concentrically disposed blunting component and needle component can then be removed from the guide member(s) and secured to a syringe or other device in a conventional manner. The guide member(s) can then be re-used to facilitate the assembly of another device.

As described with reference to FIG. 9A, the mounting end of the blunting member was inserted into the insertion tip of the needle cannula. However, in an alternative embodiment of the invention, a guide member configured to provide a guide surface that leads axially to hub aperture 40c could be disposed at the opposite end of the needle component so that the tip of blunting member 14 is aligned with, and is inserted into, the mounting end 18b of needle cannula 18 through hub 20 via aperture 40c. In such case, the blunting member hub may optionally be mounted on the blunting member before the blunting member is inserted into the needle cannula.

It will be understood that the V-shaped configuration of grooves 58 and 60 are illustrative only and any suitable groove geometry which functions to align the needle cannula 18 and blunting member 14 for assembly thereof may also be employed in the practice of this aspect of the invention. For example, the apex of guide surface 58 need not be angular in cross section as illustrated, but could be curvilinear in cross section. It will also be understood that the concentric relation between the blunting member and the needle cannula may be reversed (not shown), as discussed above in connection with FIGS. 5 and 6.

In an alternative embodiment, a guide member may be configured to define two guide surfaces comprising grooves of differing configurations. For example, a guide member 52', FIG. 9B, resembling the end-to-end joiner of guide members 50 and 52 could be formed and would thus define a guide surface that comprises two grooves 58 and 60 on the same structure. The resulting guide member 52' would thus permit the positioning of the needle cannula in guide surface 58 and the positioning of a blunting member in the groove 60 to facilitate insertion of the blunting member into the needle by moving the blunting member into the needle cannula, as suggested by arrow 56'.

Referring now to FIG. 10, in this embodiment a vertical assembly process is contemplated wherein the guide member comprises a funnel 62 which may, e.g., reciprocate in the direction of arrow 64 as described hereafter. As illustrated, the internal component, i.e., needle cannula 18, funnel 62, and external hub 20 are disposed in spaced relationship along a vertical axis B. The funnel is employed to facilitate insertion of an internal component, in this case needle cannula 18, into an external component, in this case hub 20, having a passage 38 which provides a through-bore therein. Funnel 62 defines an entry aperture 62a and an exit aperture 62b. The internal diameter of exit aperture 62b is not larger than the entrance of passage 38 into which the internal component is to be inserted, and the entry aperture 62a is larger than the exit aperture. Funnel 62 comprises an internal guide surface 62c that converges axially from the entry aperture 62a to the exit aperture 62b. In operation, funnel 62 is positioned with exit aperture 62b aligned with passage 38. The mounting end 18b of the internal component is aligned with entry aperture 62a and is advanced into the funnel. This may be achieved in a vertical assembly process by positioning the funnel vertically over the external component, positioning the internal component above the entry aperture of the funnel, and releasing the internal component so that it is pulled by gravity into the funnel. The needle will come to rest on internal shoulder 39. A second funnel having an exit aperture not larger than the through-bore of the needle may be used in a similar manner to facilitate the insertion of the

18

blunting member into the needle. The blunting member will be configured to pass through the needle and through the hub so that the blunting member hub or "nut" can be secured to the bottom end of the blunting member.

Alternatively, the needle component, i.e., the hub 20 with the needle 18 secured therein, may be inverted and the blunting member may be introduced into the mounting end of the needle through-bore. In such case, the guide member may be embodied as a split fixture having separable halves that are movable between a working configuration illustrated schematically in FIG. 11A and a separated configuration illustrated schematically in FIG. 11B. In the working configuration, an assembly fixture holds parts 162a and 162b together so that they cooperate to form a generally conical, funnel-like guide surface 162c, as shown in FIG. 11A. The fixture 162 is positioned so that the exit aperture of the guide surface (not visible in FIG. 11A) is aligned with the mounting end of a needle cannula. The tip of a blunting member 14 is then aligned with the guide surface 162c, e.g., by directing it downward from above, and is brought in contact therewith and is advanced therethrough so that it is guided to the exit aperture and then into the needle cannula. The nut on the blunting member (shown in dotted outline in FIG. 11B) is larger than the exit aperture of the guide surface 162c and cannot pass therethrough, so after the blunting member has entered the needle cannula, parts 162a and 162b are separated as suggested by the unnumbered arrows in FIG. 11A. The fixture 162 thus attains the separated configuration of FIG. 11B. The self-blunting needle device may thus be assembled and removed from the fixture 162. The fixture 162 can then be moved back to the working configuration of FIG. 11A and positioned for use in inserting another blunting member into another needle cannula.

In the embodiments of FIGS. 9A, 9B and 10, the guide member is not an integral part of the finished self-blunting needle device, so the method for the assembly of the needle device may comprise removing the assembled device from the guide member.

In the embodiments of FIGS. 1-4, the needle cannula 18 in the hub 20 may be considered the reference member because its position is fixed relative to the first guide surface (e.g., surface 40, FIG. 2A) which guides the misaligned complementary member, i.e., the blunting member 14, into the cannula through-bore.

In the embodiments of FIGS. 5 and 6, the blunting member 14' is the reference member because it is fixed in position relative to the guide surface 40' and the needle cannula 18' constitutes the complementary member.

While several preferred embodiments have been shown and described, various modifications and substitutions may be made thereto without departing from the spirit and scope of the invention. Accordingly, it is to be understood that the present invention has been described by way of illustration and not limitation.

What is claimed is:

1. A self-blunting needle cannula device comprising:

- (a) an external component comprising a needle cannula having a through-bore, a tip comprising a puncture tip, a mounting end, and an external component hub on the needle cannula spaced from the tip;
- (b) an internal component comprising an elongate blunting member having a tip defining a blunt tip, and an internal component hub on the blunting member being disposed within the through-bore of the needle cannula;
- (c) wherein the external component and the internal component are movable relative to each other between

19

- a sharpened configuration in which the blunt tip is positioned short of the puncture tip of the needle cannula to leave the puncture tip exposed, and a blunting configuration in which the blunt tip extends beyond the puncture tip of the needle cannula to effectively blunt the device;
- (d) a guide surface on the device that leads axially towards the through-bore so that the guide surface can serve as a guide for the insertion of the blunting member into the through-bore during assembly of the device; and
- a detent and groove engagement between the external component and the internal component configured to inhibit movement from the blunting configuration to the sharpened configuration.
2. The device of claim 1 wherein the guide surface converges axially from a first entry aperture larger than the through-bore to a first gate aperture not larger than the through-bore, the first gate aperture being aligned with the through-bore.
3. The device of claim 1 wherein the guide surface comprises a non-convergent surface that defines a groove that is positioned and configured to guide the blunting member into the through-bore of the needle cannula.
4. The device of claim 3 wherein the guide surface further comprises a portion that converges axially from a first entry aperture larger than the through-bore to a first gate aperture not larger than the through-bore, the first gate aperture being aligned with the through-bore.
5. The device of claim 3 or claim 4 wherein the first entry aperture has a diameter in the range of from about 0.5 to 0.009 inch and the first gate aperture has a diameter in the range of from about 0.203 to 0.006 inch.
6. The device of claim 2 wherein the needle cannula defines a longitudinal axis and wherein at least a portion of the guide surface defines an angle  $\alpha$  relative to the needle cannula axis and wherein the angle has a magnitude in the range of from about 5 to 75 degrees.
7. The device of claim 2 or claim 3 comprising a guide member disposed at the mounting end of the needle cannula, the guide member defining the guide surface.
8. The device of claim 7 wherein the guide member is disposed within the external component hub.
9. The device of claim 7 wherein the guide member is integrally formed as part of the external component hub.
10. The device of claim 9 wherein the guide member comprises an alignment lug formed on the external component hub.
11. The device of claim 3 comprising a guide member having a first end at which the first guide surface is formed and an opposite, second end at which is formed a second entry aperture larger than the needle cannula and a second guide surface that converges axially to a second gate aperture smaller than the second entry aperture but not smaller than the needle cannula, the guide member further comprising a passage extending between and axially aligned with the first and second gate apertures, the needle cannula extending through the second gate aperture and the mounting end of the needle cannula being mounted within the passage, and wherein the second guide surface converges from the second entry aperture towards the bore to the second gate aperture, to serve as a guide for the insertion of the mounting end of the needle cannula into the passage during assembly of the device.
12. The device of claim 11 wherein the first gate aperture is smaller than the passage in the guide member and smaller than the needle cannula so that the guide member defines in the passage a stop shoulder at the first gate aperture.

20

13. The device of claim 11 wherein the second entry aperture has a diameter in the range of from about 0.5 to 0.009 inch and the second gate aperture has a diameter in the range of from about 0.203 to 0.006 inch.
14. The device of claim 11 wherein the second guide surface defines an angle  $\alpha$  relative to the needle cannula axis and wherein the angle has a magnitude in the range of from about 5 to 75 degrees.
15. The device of any one of claims 1-4 in combination with a syringe comprising an actuation member for moving the device from a sharpened configuration to a blunted configuration.
16. The device of claim 1 wherein the detent and groove engagement is dimensioned and configured to releasably maintain the device in the sharpened configuration prior to its movement to the blunted configuration.
17. A method for assembling a self-blunting needle device for a syringe, the device comprising an internal component comprising a blunting member and an external component comprising a needle cannula having an axially-extending through-bore therein, the method comprising advancing the blunting member into contact with a guide surface configured to lead axially to the through-bore to guide the blunting member into the bore and advancing the blunting member along said guide surface and into the through-bore without engaging a catch surface perpendicular to the needle cannula, to produce an assembled device.
18. The method of claim 17 comprising advancing the internal component into contact with a non-convergent guide surface.
19. The method of claim 17 comprising advancing the internal component into contact with an axially convergent guide surface.
20. The method of claim 19 wherein the guide surface defines an entry aperture that is larger than the through-bore of the external component and converges to a gate aperture that is not larger than the through-bore of the external component, the gate aperture facing and being aligned with the through-bore, the method comprising aligning the internal component with the entry aperture and advancing the internal component towards the external component so that the internal component passes through the entry aperture, into contact with the guide surface and then through the aperture and into the bore.
21. The method of claim 17, claim 18 or claim 19 comprising contacting the external component with a first guide surface and contacting the internal component with a second guide surface.
22. The method of claims 17, 18, 19 or 20 wherein the guide surface is provided by a non-integral guide member and wherein the method comprises removing the assembled device from the guide member.
23. The method of claim 22 wherein the external component comprises a cannula having a tip and a mounting end mounted in a hub, the hub defining an aperture that permits access to the through-bore by the internal component, wherein the guide member comprises a funnel having a gate aperture and an exit aperture and wherein the method comprises aligning the gate aperture of the funnel with the through-bore at the tip of the cannula, passing the internal component through the guide member and removing the assembled device from the guide member.
24. The method of claim 23 further comprising securing a nut to the internal component after the internal component passes through the guide member.
25. The method of claim 17 further comprising mounting the self-blunting needle device on a syringe.

21

26. A method for assembling a self-blunting needle device comprised of (i) an external component comprising a needle cannula having a through-bore, a puncture tip and a mounting end and a guide member having a first end and a second end and a passage that extends axially from the first end to the second end and further comprising at the first end a first guide surface that leads axially to the passage and at the second end a second guide surface that leads axially to the passage, wherein the passage is sized to receive the needle cannula; and (ii) an internal component comprising an elongate blunting member having a blunt tip, and, after assembly, being disposed within the through-bore of the needle cannula;

the method comprising the steps of:

- (a) disposing the needle cannula with its mounting end disposed towards and in alignment with the second guide surface and advancing the needle cannula into contact with the second guide surface and into the passage and into alignment with the first gate aperture,
- (b) positioning a guide member having a guide surface relative to the external component so that the guide surface leads axially to the through-bore; and

22

- (c) advancing the blunting member into contact with the guide surface to guide the blunting member into the through-bore of the needle cannula.

27. The method of claim 26 comprising providing a guide member having a first end and a second end and a passage that extends axially from the first end to the second end and further comprising at the first end a first guide surface that leads axially to a first gate aperture aligned with the passage and at the second end a second guide surface that leads axially to the passage, wherein the passage is sized to receive the needle cannula,

the method further comprising, before steps (a) and (b), disposing the needle cannula with its mounting end disposed towards and in alignment with the second guide surface and advancing the needle cannula into contact with the second guide surface and into the passage and into alignment with the first gate aperture.

28. The method of claim 26 further comprising the steps of installing the self-blunting needle device in a medical fluid-handling device comprising an actuation member for moving the device between the sharpened configuration and the blunted configuration.

\* \* \* \* \*